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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,127	07/30/2001	William J. Curatolo	PCI0754AJTJ	1383
7590	04/20/2004		EXAMINER	
Gregg C. Benson Pfizer Inc. Patent Department MS 4159, Eastern Point Road Groton, CT 06340			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/918,127	Applicant(s) CURATOLO ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 19-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 35-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/21/03</u> | 6) <input type="checkbox"/> Other: _____  |

### ETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment/remarks filed 01/12/04. Complete listing of the pending claims is received. IDS filed 07/21/03 is also received.

Observation regarding listing of claims:

Claims 1-3 were amended April 25 2003. Thus, it would have been proper to append --- previously amended--- to claims 1-3 instead of "previously presented."

Observation regarding IDS:

Copending applications are listed as prior art on the form PTO 1449. Copending applications are not prior art.

### *Claim Rejections - 35 USC § 112*

1. Claims 49-55 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Applicants' arguments filed 01/12/04 have been fully considered but they are not persuasive.

Applicants state the term cellulosic is well known in the art to the person of skill in the art and that a complete listing of what materials make up cellulosic need not be given and cited In re Grimme, 124 USPQ 499, 502 (CCPA 1960). However, the question is, are the cellulose polymers listed in the disclosure derived from, made from or related to cellulose or are they cellulose? It would appear that the listing provided a list of materials that are known cellulose

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materials and not materials that are related or made from or produced from cellulose that may be different form cellulose. Applicants' consideration of the issue raised is respectfully requested.

Examiner thanks applicants for correcting the seeming typographical error by correcting the dependencies of claims 89-96.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-10, 17, 18, 35-51, 56-86 and 88 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski (WO 99/14204).

5. Applicants' arguments filed 01/12/04 have been fully considered but they are not persuasive.

Specifically applicants argue that Sikorski does not disclose a solid amorphous dispersion.

It is respectfully noted that the instant invention in generic claim 1 is a composition that comprises a solid amorphous dispersion and concentration-enhancing polymer selected from the group consisting of hydroxypropyl methyl cellulose, etc. Sikorski starts from a powder form of CETP and powder is amorphous except powder is shown not to be amorphous to the contrary.

Secondly, spray drying, a process of tablet formation results in formation of dispersion.

Therefore, the rejection over Sikorski is maintained.

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6. Claims 1-10, 17, 18 and 35-96 are rejected under 35 U.S.C. 102(e) as being anticipated by Appel et al. (US 6,706,283)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

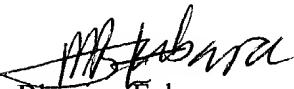
Appel discloses a composition comprising concentration-enhancing polymers and solid amorphous dispersion of anti-hypercholesterolemic atorvastatin calcium (column 6, line 34 to column 7 line 44; column 8, lines 31-64; column 9, lines 12-29). Appel meets the limitations of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
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